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EXAMINER

MILANO, M
ART UNIT PAPER NUMBER

3308

11

DATE MAILED: 06/02/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3/7/97☐ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-117 is/are pending in the application.
Of the above, claim(s) 32-41 & 98-117 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-35 & 42-97 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948 (substitute)
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 14, 17, 19, 24, 25, 31, 45, 58, 74, 82, 87, 88, 95 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims which recite that the tube comprises a vascular graft or intraluminal graft are not understood. It is not clear if the tube is intended to have an additional graft layer or if the tube is intended to be the vascular graft or intraluminal graft itself. Regarding claims 17 and 31, "the second circumference" lacks antecedent basis.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-5, 24-30, 33-35, 42-49, 51-55, 57-61, 63-67 and 69-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee, 5,123,917. The expansion limit of the graft layer is reached due to the limit of expansion of the stent. The stent will permit only a predetermined expansion due to the stent configuration and structure. Additional application of internal pressure

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will not expand the stent or graft layer/tube. The device does not appear to have a recoil so the "or less" limitation is met by the zero (0) recoil of the tube.

4. Claims 1,2,5,24-30,33-35,42-48,51-54,58-60,63-66,69,70,72,74,76,78,80,82,84 and 86-97 are rejected under 35 U.S.C. 102(b) as being anticipated by Rhodes, 5,122,154. The expansion limit of the graft layer is reached due to the limit of expansion of the stent. The stent will permit only a predetermined expansion due to the stent configuration and structure. Additional application of internal pressure will not expand the stent or graft layer/tube. The device does not appear to have a recoil so the "or less" limitation is met by the zero (0) recoil of the tube.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 6-16, 19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee ('917) in view of Eilentropp, 4,791,966. Lee teaches all aspects of the claimed invention except for the helical wrapped PTFE layer. The Lee outer layer is a porous PTFE tube applied over the inner tubular layer and stent. Eilentropp teaches a PTFE tube formed by a helical layer of wrapped PTFE material. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the outer layer of Lee of helically wrapped PTFE as

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taught by Eilentropp, because the helical layered tube would have been merely an alternate and analogous method of forming a tube on the Lee device.

7. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee ('917) in view of Eilentropp ('966) as applied to claim 14 above, and further in view of Summers ('445). The difference between the modified Lee device and the claimed invention is the use of a branched stent/graft with three ends. Summers teaches the use of a stent which can have a straight or branched configuration depending on the vessel that is to be supported. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the modified Lee stent/graft with a branched, three end configuration, because the branched configuration would have enabled the stent/graft to support and repair a branched vessel as taught by Summers. It should be noted that the branched, three end configuration would inherently form a larger and smaller end on the stent graft (i.e., tapered tube between first and second ends).

8. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee ('917) in view of Summers, 5,607,445. The difference between Lee and the claimed invention is the use of a branched stent/graft with three ends. Summers teaches the use of a stent which can have a straight or branched configuration depending on the vessel that is to be supported. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have formed the Lee stent/graft with a branched, three end configuration, because the branched configuration would have enabled the stent/graft to support and repair a branched vessel as taught

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by Summers. It should be noted that the branched, three end configuration would inherently form a larger and smaller end on the stent graft (i.e., tapered tube between first and second ends).

9. Claims 20, 50, 56, 62 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee alone or Lee in view of Eilentropp. The difference between Lee and the claimed invention is the use of sutures to secure the stent/graft. The Examiner takes Notice that sutures would have been well known in the art at the time of the invention to secure a graft or stent/graft to a vessel to prevent migration of the device within the vessel. Therefore, it would have been obvious to one of ordinary skill in the art to have used sutures for enhanced securement of the Lee stent/graft to the vessel.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

11. Any inquiry concerning this communication should be directed to Michael Milano at telephone number (703) 308-2496.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 3300 Receptionist whose telephone number is (703) 308-0858.

Milano.mm



Michael J. Milano
Primary Examiner
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